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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/723,307	11/27/2000	Emanuel Calenoff	21417/91482	5598

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EXAMINER	
ZHOU, SHUBO	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 10/02/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/723,307	CALENOFF ET AL.	
	Examiner	Art Unit	
	Shubo "Joe" Zhou	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-27 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-27 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The art unit designated for this application has changed. Applicant(s) are hereby informed that future correspondence should be directed to Art Unit 1631.

Sequence Rules Compliance

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 because of the following reasons. Firstly, many of those sequences are not identified by a sequence identifier ("SEQ ID NO:X") such as some of the sequences in Fig. 2: daNktglk, peNrtdlh, and elsewhere. Applicants are reminded that it is required that SEQ ID Nos be amended into the specification at each sequence, and that when a sequence is presented in a drawing, regardless of the format or the manner of presentation of that sequence in the drawing, the sequence must still be included in the Sequence Listing and the sequence identifier must be used, either in the drawing or in the Brief Description of the Drawings. Secondly, these sequences that are not identified by a sequence identifier are not listed in the Sequence Listing. A paper copy and computer readable form of the amended Sequence Listing, as well as a statement under 37 CFR 1.821(f) are required. Applicants are given the same response time regarding this failure to comply as that set forth to respond to this office action. Failure to comply with these requirements will result in ABANDONMENT of the

application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a).

Restriction/Election Requirement

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claim 1, drawn to a method of identifying candidate cancer antigen, classified in Class 435, subclass 7.1.

II. Claims 2-11, 24, and 27, drawn to cancer antigens, classified in Class 424, subclasses 184.1.

III. Claim 12, drawn to an immunoassay, classified in Class 435, subclass 7.1.

IV. Claim 13, drawn to a diagnostic method, classified in Class 436, subclass 500.

V. Claims 14-15, drawn to molecules that specifically reactive with a group of cancer antigens. Since the chemical nature of the molecules is un-known, they cannot be properly classified.

VI. Claim 16, drawn to methods of delivering cancer cell molecules involving the use of the molecules of Group V. Since the chemical nature of the molecules is un-known, they cannot be properly classified.

VII. Claim 17, drawn to methods of determining degree of cancer expression involving assaying the molecules of Group V. Since the chemical nature of the molecules is un-known, they cannot be properly classified.

VIII. Claim 18, drawn to methods of determining type of cancer cells using the molecules of Group V. Since the chemical nature of the molecules is un-known, they cannot be properly classified.

IX. Claims 19-22, drawn to cancer imaging reagent comprising the molecules of Group V. Since the chemical nature of the molecules is un-known, they cannot be properly classified.

X. Claims 23, drawn to cancer therapeutic reagent comprising the molecules of Group V. Since the chemical nature of the molecules is un-known, they cannot be properly classified.

XI. Claims 25, drawn to a therapeutic construct comprising a nucleotide sequence encoding an antigen, classified in Class 435, subclass 320.1.

XII. Claims 26, drawn to a method of producing immunity using a therapeutic construct comprising a nucleotide sequence encoding an antigen, classified in Class 435, subclass 7.1.

The inventions are distinct, each from the other because of the following reasons:

The sets of invention groups (I-IV), (V-X) and (XI-XII) are independent with respect to each other because the methods as claimed are distinct both physically and functionally, require different process steps, reagents and parameters, and produce different products. The products as claimed, i.e. the antigens, the molecule that specifically interacts with the antigen, etc., are distinct both physically and functionally also, and require different process steps, reagents and parameters to produce. Consequently, these inventions have acquired a separate status in the art as a separate subject for inventive effect and are usually published separately. The search for each of the above inventions is not co-extensive particularly with regard to the literature search. Thus, examination of the invention groups together would impose an undue search burden to the Office.

The inventions of Groups I and II are related as product and process of making. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process as claimed can be used to make other and materially different product or (2) the product as claimed can be made by another and materially different process (MPEP §806.05(f)). In the instant case, the antigens of Group II can be produced by the process of invention of Group I by identifying testing an immunogenic peptide in vivo. Alternatively, since the sequences of the antigens are known or can be known by chemical sequencing, the antigens can be made by pure in vitro chemical synthesis, which is clearly a distinct way of making.

The inventions of Groups II and (III-IV) are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the antigens of Group II can be used in the distinct processes of the inventions of Groups (III and IV), which are directed to an immunoassay in biological fluids and diagnostics, respectively. These processes are clearly distinct because they involve different steps and require distinct reagents.

The inventions of Groups V and (VI-X) are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the molecule of Group V that is specifically reactive with an antigen can be used in the distinct processes of the inventions of Groups (VI-X)), which are directed to delivering

cancer cell molecules, determining degree of cancer expression, determining type of cancer cells, respectively. These processes are clearly distinct because they involve different steps and require distinct reagents.

The inventions of Groups XI and XII are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the nucleic acid construct of Group XI can be used in the process of Group XII, which is directed to a method of producing immunity. Alternatively, the nucleic acid construct can be used to express antigens which can then be used to raise antibodies. This is clearly a distinct process of using the nucleic acid construct.

Because these inventions are independent/distinct for the reasons given above and have acquired a separate status in the art and thus are usually published separately in the literature because of their recognized divergent subject matter, there would be undue search burden if they were examined together. Therefore, restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR § 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be

accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Applicant is further reminded that a fully responsive communication will comprise a proper election of a group, and sequences, as well as compliance with the sequence rules as set forth above. Examination cannot proceed without a complete response.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to: Shubo "Joe" Zhou, Ph.D., whose telephone number is (703) 605-1158. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703) 308-4028. Any inquiry of a general nature or relating to the status of this application should be directed to the Technical Center receptionist whose telephone number is (703) 308-0196.

S. "Joe" Zhou, Ph.D.

JOHN S. BRUSCA, PH.D
PRIMARY EXAMINER